IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	:	
ex rel. JOHN UNDERWOOD,	:	
et al.,	:	
Plaintiffs,	:	
v.	:	**CIVIL ACTION NO. 03-3983**
	:	
GENENTECH, INC., et al.,	:	
Defendants.	:	

Diamond, J. **June 2, 2010**

MEMORANDUM

The United States having declined to intervene in this *qui tam* action, the Relator – who is continuing the lawsuit – seeks to amend his Complaint to add new allegations purportedly based on documents the Department of Justice obtained during its six year investigation of this matter. *(Doc. No. 63.)* Defendant has moved to dismiss, arguing that the Complaint does not meet Rule 9(b)'s heightened pleading requirement. *(Doc. No. 73.)* Defendant also asks me to bar any amendment as an impermissible attempt to bolster Relator's defectively pled Complaint. *(Doc. No. 68.)*

Defendant bases its Rule 9(b) argument on Relator's failure to identify in his Complaint a specific false claim actually submitted to the Government. There is no authority in this Circuit requiring such particularized pleading, however, especially where, as here, the Relator has alleged that the Defendant itself did not submit the false claims, but induced third parties to do so. Accordingly, I conclude that the Complaint Relator seeks to amend – which includes detailed allegations of Defendant's fraudulent scheme – passes muster under Rule 9(b).

Even though the law usually does not allow a *qui tam* relator to save an inadequately pled complaint by adding amendments based on discovery obtained from the defendant, there is no authority barring such amendments based on discovery obtained from the Government. Accordingly,

I conclude in the alternative that regardless of whether Relator's Complaint is adequately pled, he may amend with discovery he obtained from the Government.

I will thus deny Genentech's Motion to Dismiss (Doc. No. 73) and grant Relator's Motion to Amend (Doc. No. 63).

I. BACKGROUND

Defendant Genentech, Inc. is a California-based biotechnology company that manufactures and markets Rituxan, a prescription drug the Food and Drug Administration has approved for the treatment of non-Hodgkins lymphoma and chronic lymphocytic leukemia. *(Doc. No. 15 ¶¶ 3, 17-20.)* From 1997 until 2005, Genentech employed Relator John Underwood as a sales manager and senior hospital systems specialist. *(Id. ¶ 2.)*

In 2003, Relator informed the DOJ that Genentech was defrauding Medicare and Medicaid through an "off-label" marketing and kickback scheme: Genentech bribed health care providers to prescribe Rituxan for uses other than the treatment of lymphoma or leukemia. *(Doc. No. 63, Ex. A ¶¶ 10, 14.)* According to Relator, off-label Rituxan prescriptions generated hundreds of millions of dollars in revenue to Genentech, comprising more than half the Medicare and Medicaid monies paid to the Company. *(Id. ¶ 14.)*

On July 3, 2003, Relator filed under seal a *qui tam* Complaint, alleging violations of the False Claims Act through underlying violations of the Medicare and Medicaid Fraud and Abuse Act. See 31 U.S.C. §§ 3729 *et seq.*; 42 U.S.C. §§ 1320 *et seq*. As the False Claims Act requires, Relator served the United States – on whose behalf he was proceeding – with his Complaint so that it could decide whether to intervene in the case. *(Doc. No. 1.)* He filed his First Amended Complaint under seal on November 8, 2005. *(Doc. No. 15.)*

Beginning in 2003, the DOJ investigated Relator's allegations, obtaining some seven million

documents from other federal agencies and from Genentech itself. On September 25, 2009, the United States filed a Notice of Election to Decline Intervention. *(Doc. No. 29.)* To help him decide whether to proceed with this action, Relator subpoenaed the seven million documents from the DOJ. See Fed. R. Civ. P. 45; Doc. No. 46. Although the DOJ provided Relator with documents it had obtained from other federal agencies, it declined, absent court order, to provide those documents it had obtained directly from Genentech. *(Doc. No. 48.)* When the DOJ notified Genentech of the subpoena, the Company moved for protective relief. *(Doc. No. 45.)*

After a hearing on December 17, 2009, I denied protective relief, ordered the DOJ to comply with Relator's third party subpoena, and granted Genentech's Motion to Unseal the Complaint. *(Doc. Nos. 54, 56.)* The First Amended Complaint and the docket were unsealed on December 31, 2009. Pursuant to the Parties' agreement, I issued a Scheduling Order on January 8, 2010 requiring Relator to serve the "operative complaint" in this matter "within 90 days of the delivery to counsel for the Relator of the records subpoenaed . . . consisting of the documents produced to the government by Defendant Genentech, Inc. during its investigation." *(Doc. No. 58 ¶ 1.)*

Relator filed the instant Motion for Leave to File Second Amended Complaint on April 15, 2010. *(Doc. No. 63.)* After reviewing Genentech's response in opposition, I ordered the Parties to submit memoranda addressing whether the First Amended Complaint was adequate under Rule 9(b). *(Doc. No. 72.)* Genentech instead moved to dismiss the First Amended Complaint, arguing that it did not pass muster under Rule 9(b). *(Doc. No. 73.)* In response to Genentech's Motion, the United States submitted a "Statement of Interest," taking strong exception to Genentech's construction of Rule 9(b)'s pleading requirements. *(Doc. No. 75.)*

II. RELATOR'S ALLEGATIONS

As I explain below, although the First and Second Amended Complaints differ, both include

the same core conspiracy charges – that Genentech carried out a fraudulent scheme to profit from off-label Rituxan prescriptions written for Medicare and Medicaid patients. Both pleadings set out the two ways that Genentech engineered this scheme: (1) pressuring its sales staff illegally to market off-label uses for Rituxan prescriptions; and (2) paying illegal kickbacks – tropical vacations or honoraria – to induce and reward physicians who prescribed off-label Rituxan.

In the First Amended Complaint, Relator alleges that Genentech's scheme began in 2000 and continued until "at least December 2002." *(Doc. No. 15 ¶ 18.)* The Complaint included seven Counts:

> (1) "deliberate avoidance of FDA regulations," or active concealing of the off-label Rituxan prescriptions from federal regulators;
>
> (2) "false statements to physicians regarding Rituxan" by Genentech employees with reference to the safety and efficacy of the medication;
>
> (3) illegal kickbacks to physicians who prescribe large amounts of Rituxan prescriptions;
>
> (4) off-label Rituxan sales to the Veteran's Administration;
>
> (5) "violating state formularies," review boards' rules about which uses of prescription drugs were eligible for Medicare reimbursement;
>
> (6) "avoiding [federal Medicare and Medicaid] price controls based on therapeutic equivalency"; and
>
> (7) illegal kickbacks to physicians who prescribe large amounts of Herceptin, another Genentech medication used for the treatment of breast cancer.

(Doc. No. 15 ¶¶ 23-51.)

The Second Amended Complaint includes only two Counts, both untitled, in which Relator consolidates and refines the allegations in Counts One, Two, and Three of the First Amended Complaint. The allegations in Counts Four, Five, Six, and Seven are not included in the Second

Amended Complaint. In Count One, Relator alleges that between 2000 and 2005, Gententech's off-label Rituxan marketing "caused tens of thousands of fraudulent claims to be submitted to the Medicare and Medicaid programs." *(Doc. No. 63, Ex. A, ¶¶ 53-55.)* In Count Two, Relator alleges that during this same period, Genentech paid bribes to physicians to prescribe Rituxan for off-label uses – funding seminars in "prime vacation locations" and paying honoraria. *(Id. ¶¶ 56-62.)* Thus, although both the First and the Second Amended Complaints are based on the same statutes, the most significant difference between them is the narrowing and refinement of the causes of action.

The Relator alleges that Genentech bribed doctors to prescribe Rituxan to their Medicare/Medicaid patients for off-label use in violation of the Medicare and Medicaid Fraud and Abuse Act. 42 U.S.C. § 1320a-7(b). This statute (unlike the False Claims Act) does not provide for private enforcement. United States ex rel. Schmidt v. Zimmer, Inc., No. 00-1044, 2005 U.S. Dist. LEXIS 15648, at *9 n.5 (E.D. Pa. July 29, 2005). The Relator contends, however, that these bribes resulted in the presentation of many thousands of fraudulent Medicare and Medicaid reimbursement claims in violation of the False Claims Act. 31 U.S.C. §§ 2729 *et seq*.

The Second Amended Complaint also includes new factual allegations. For instance, Relator has added updated financial information. In the First Amended Complaint, Relator alleged that 30 percent of Genentech's $1.07 billion in 2002 Rituxan sales was for on-label, FDA-approved purposes and that 70 percent was for off-label prescriptions. *(Doc. No. 15 ¶ 14.)* In the Second Amended Complaint, Relator adds that "Genentech's total sales of Rituxan for the period encompassed by this Complaint rose sharply, from $262.7 million in 1999 to over $1.8 billion in 2005." *(Doc. No. 63, Ex. A, ¶ 23.)* Extending the conspiracy's duration to 2005, Relator also alleges that "between the beginning of 2000 and the end of 2005, the Medicare program paid Genentech well over $1.5 billion for Rituxan for senior citizens suffering from" non-Hodgkins lymphoma alone. *(Id.*

¶ *24.)*

Many of the new factual allegations in the Second Amended Complaint relate to Genentech's efforts to promote off-label Rituxan use. In the First Amended Complaint, Relator alleged that "Defendants exerted significant pressure on their sales representatives, including Relator, to increase off-label uses of Rituxan by all possible means." *(Doc. No. 15 ¶ 19.)* Purportedly relying on Genentech documents, Relator adds detail to this allegation. For example, in 2003, Genentech set a $300 million target increase in Rituxan sales, with just $75 million of that amount to come from legal on-label uses. *(Doc. No. 63, Ex. A ¶ 38.)* A Genentech sales representative expressed concern in a 2002 "emergency" email that Mount Sinai Medical Center was going to adopt "protocol that limits the use of Rituxan to only on-label use," because "85% of Rituxan sales come[] from off indication use." *(Id. ¶ 51.)*

Relator also adds detail to the kinds of bribes Genentech allegedly paid to promote Rituxan's off-label use. In the First Amended Complaint, Relator alleged that the Genentech sales department disguised these bribes as "consultantships although [they were] unrelated to any scientific or educational activity," "cash payments, travel benefits, entertainment, and other benefits." *(Doc. No. 15 ¶ 19.)* In the Second Amended Complaint, Relator adds that Genentech "invit[ed] 'key' oncologists, large prescribers of Rituxan, on all-expenses paid trips to prime vacation locations and pa[id] them honoraria . . . to reward them for high use of Rituxan and to persuade them to continue prescribing it." *(Doc. No. 63, Ex. A ¶ 57.)*

III. LEGAL STANDARDS

A. *Qui Tam* Actions

The False Claims Act imposes liability upon those who present to the Government – or cause

to be presented – false or fraudulent claims for payment. 31 U.S.C. § 3729(a)(1); see Hutchins v. Wilentz, 253 F.3d 176, 182 (3d Cir. 2001) *cert. denied*, 536 U.S. 906 (2002).

The FCA's *qui tam* provisions allow a private individual – the relator – to initiate a *qui tam* lawsuit on behalf of the United States. 31 U.S.C. § 3730. See United States ex rel. S. Prawer & Co. v. Fleet Bank, 24 F.3d 320, 324 n.7 (1st Cir. 1994) ("*Qui tam* is an abbreviation for *qui tam pro domino rege quam pro siepso*, which literally means he who as much for the king as for himself.") The relator must first serve the DOJ with his or her complaint, which remains under seal for sixty days, or more if extensions are granted. 31 U.S.C. § 3730(b)(2). If the United States elects to intervene, it assumes control of the suit, adopting any or all of the relator's allegations. Should the United States prevail, the relator is entitled to 15 to 25 percent of any recovery. 31 U.S.C. § 3730(c)(1), (d)(1). If the United States does not intervene, the relator may still proceed. 31 U.S.C. § 3730(b)(2), (b)(4)(B), (c)(3). The relator would then be entitled to 25 to 30 percent of any recovery made on behalf of the United States. 31 U.S.C. § 3730(d)(2). Even after the United States elects not to intervene, it may, during the pendency of the litigation, reassert its intervention right. 31 U.S.C. § 3730(b)(1) and (c).

B. Pleading Requirements

The Federal Rules usually require a plaintiff to present only "a short and plain statement" of his or her claim. Fed. R. Civ. P. 8(a). Rule 9(b) provides, however, that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). This heightened pleading standard is intended "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach.

Corp., 742 F.2d 786, 791 (3d Cir. 1984). The Third Circuit has cautioned against overemphasizing the specificity requirement:

> Under Fed. R. Civ. P. 9(b), plaintiffs must plead with particularity the circumstances of the alleged fraud. They need not, however, plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud.

Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (internal citations omitted).

Although the Third Circuit has suggested that a heightened standard applies to False Claims Act complaints, it has not yet defined that standard. See United States ex rel. St. John LaCorte v. Smithkline Beecham Clinical Lab., 149 F.3d 227, 234 (3d Cir. 1998). In upholding a summary judgment dismissal, however, the Third Circuit cited with approval the 11th Circuit's application of Rule 9(b):

> [T]he court held that a False Claims Act plaintiff cannot 'merely . . . describe a private scheme in detail but then . . . allege simply and without any stated reason for his belief that claims requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government.'

United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432, 439-40 (3d Cir. 2004) (citing United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002)). In the view of the Clausen Court, "if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government." 290 F.3d at 1311.

Other Circuits have followed Clausen, holding that the identification in the complaint of a

false claim "is the *sine qua non* of a False Claims Act violation." Id.; see, e.g., United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004); United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 727 (10th Cir. 2006). The Fifth Circuit, however, has rejected this requirement:

> [A] plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted. To require these details at pleading is one small step shy of requiring production of actual documentation with the complaint . . . We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

United States ex rel. Grubbs v. Ravikumar Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009).

District courts in this Circuit are divided in their interpretations of Rule 9(b). Some have dismissed *qui tam* complaints that did not identify an actual false claim. See United States ex rel. Barlett v. Tyrone Hosp., Inc., 234 F.R.D. 113, 120 (W.D. Pa. 2006); United States ex rel. Schmidt v. Zimmer, Inc., No. 00-1044, 2005 U.S. Dist. LEXIS 15648, at *1, 7-8 (E.D. Pa. July 29, 2005) (citing Quinn and Clausen). Other courts have distinguished Quinn, noting that the decision upheld a grant of summary judgment and included criticisms of Clausen. See United States ex rel. Singh v. Bradford Reg'l Med. Ctr., No. 04-186, 2006 U.S. Dist. LEXIS 65268 (W.D. Pa. Sept. 13, 2006); United States ex rel. Landsberg v. Levinson, No. 03-1429, 2006 U.S. Dist. LEXIS 66689 (W.D. Pa. Feb. 13, 2006); Gibbons ex rel. United States v. Kvaerner Phila. Shipyard, Inc., No. 05-685, 2006 U.S. Dist. LEXIS 5172 (E.D. Pa. Feb. 10, 2006). In Singh, for instance, the Court held that requiring the pleading of particularized evidence of a false claim contravenes the Third Circuit's "flexible"

interpretation of Rule 9(b), and "would effectively negate the Third Circuit's instruction that 'Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" 2006 U.S. Dist. LEXIS 65268 at *21 (citing Seville, 742 F.2d at 791).

Significantly, in the instant case,

> [t]he United States submits that the identification of specific false claims is not an absolute prerequisite to satisfying thing particularity requirements of Rule 9(b) in F[alse] C[laims] A[ct] cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude that Rule 9(b) is satisfied.

(Doc. No. 75 at 1.)

Finally, there are limited exceptions to the heightened *qui tam* pleading standards:

> It is possible that the pleading requirements of Rule 9(b) may be relaxed in certain circumstances - when, for instance, the facts relating to the fraud are peculiarly within the perpetrator's knowledge.

United States ex rel. Doe v. Dow Chem. Co., 343 F.3d 325, 330 (5th Cir. 2003); accord Karvelas, 360 F.3d at 229; United States ex rel. v. St. Luke's Hosp., Inc., 441 F.3d 552, 559 (8th Cir. 2006). These same courts have refused to apply a relaxed pleading standard, however, when the evidence of the defendant's fraud is available from the Government. See Karvelas, 360 F.3d at 230 ("In many of these cases, the information needed to fill the gaps of an inadequately pleaded complaint will be in the government's hands."); see also United States ex rel. Russell v. Epic Healthcare Mgmt. Group, 193 F.3d 304, 308 (5th Cir. 1999) (refusing the plaintiff's request to take discovery from the defendant to bolster his complaint "because documents containing the requisite information were possessed by other entities, such as the Healthcare Financing Administration [now the Centers for

Medicare and Medicaid Services])."

C. Amending the *Qui Tam* Complaint

Although the Third Circuit has yet to address the issue, other Circuits have held that a relator whose *qui tam* complaint is inadequate under Rule 9(b) may not amend to add new allegations based on discovery the relator obtained from the defendant. See, e.g., Karvelas, 360 F.3d at 229, 231 (listing cases). The First Circuit believes that this restriction is rooted in the *qui tam* action's unique conferral of standing on an uninjured party (the relator) to bring suit on behalf of the injured party (the United States):

> [T]he reluctance of courts to permit *qui tam* relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a *qui tam* plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs.

Karvelas, 360 F.3d at 231 (internal quotation omitted); see also Clausen, 290 F.3d at 1313-14 n.24 ("When a plaintiff does not specifically plead the minimum elements of [his] allegation, it enables [the plaintiff] to learn the complaint's bare essentials through discovery and may needlessly harm a defendant['s] goodwill and reputation . . .").

Courts have thus refused to allow discovery from the defendant to bolster an inadequate *qui tam* complaint:

> [T]he False Claims Act grants a right of action to private citizens only if they have independently obtained knowledge of fraud. See 31 U.S.C. § 3730(e)(4). With this requirement the government seeks to purchase information it might not otherwise acquire. It must decide on review of the sealed complaint whether to take the case over. A special relaxing of Rule 9(b) is a *qui tam* plaintiff's ticket to the discovery process that the statute itself does not contemplate.

Russell, 193 F.3d at 309; accord United States ex rel. Godfrey v. KBR, Inc., 2010 U.S. App. LEXIS 224, at *11 (4th Cir. Jan. 6, 2010) (rejecting the plaintiff's suggestion "that he should be able to ferret out that kind of detail through discovery" to cure an otherwise deficient *qui tam* complaint).

IV. DISCUSSION

A. The First Amended Complaint Comports with Rule 9(b)

In his First Amended Complaint, Relator details Genentech's scheme to cause false claims to be presented to the Government: from 2000 through "at least December 2002," the Company bribed doctors to write many thousands of off-label Rituxan prescriptions for their Medicare/Medicaid patients; claims were then presented to the Government for payment. *(Doc. No. 15 at ¶ 18.)* Although these allegations are sufficient "to place the defendant[] on notice of the precise misconduct with which [it is] charged," Genentech believes the pleading is inadequate because it does not identify a false claim actually submitted to the Government. Seville, 742 F.2d at 791. Relying on Clausen and subsequent decisions, Genentech argues that "courts both within and outside the Third Circuit have overwhelmingly held that a relator is not entitled to proceed past the motion-to-dismiss stage if he cannot connect allegations of fraud to the submission of specific false claims." *(Doc. No. 73 at 9.)*

Clausen and its progeny are premised on the belief that dishonest intentions, with nothing more, are too easily alleged. Requiring the relator to plead the submission of an actual false claim will thus discourage baseless, "parasitic" *qui tam* litigation. Karvelas, 360 F.3d at 225. As the Government observes, however, when "the marketing scheme [to promote a drug's unauthorized use by Medicare/Medicaid patients] is large enough in scope . . . [a]bsent extraordinary circumstances, the foreseeability that the drug would be billed to the Government by at least some prescribers can

be presumed." *(Doc. No. 75 at 3 n.2.)* In the instant case, Relator has alleged such a wide-ranging "marketing scheme," spanning at least three years, thousands of Medicare/Medicaid patients, and the off-label use of Rituxan costing hundreds of millions of dollars. Accordingly, in the Government's view, the inevitable submission of false claims for Medicare and Medicaid services "can be presumed." *(Id.)*

Even if I were not prepared to accept the Government's invitation – and "presume" the submission of false claims – I would be equally unprepared to apply Clausen's "actual false claim" requirement here. Genentech ignores that the relators in Clausen and its progeny alleged that the defendant companies themselves had submitted false claims *directly* to the Government. Clausen, 290 F.3d at 1303; Karvelas, 360 F.3d at 223; United States ex rel. Schmidt v. Zimmer, Inc., No. 00-1044, 2005 U.S. Dist. LEXIS 15648, at *7-8 (E. D. Pa. July 29, 2005). Given that these relators, like virtually all relators, were present or former employees of those companies, courts thought it reasonable to require the relators to identify at least one of their employers' false claims.

In the instant case, however, Relator alleges that Genentech corruptly induced *others* to submit false claims to the Government. As the United States argues, in "off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator 'need not allege the details of particular claims, so long as the complaint as a whole is sufficiently particular to pass muster under the FCA.'" See Doc. No. 75 at 3 (citing United States ex rel. West v. Ortho-McNeil Pharm., Inc., 538 F. Supp. 2d 367, 390 (D. Mass. 2008) (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007))); accord Strom ex rel. United States v. Scios, Inc., 676 F. Supp. 2d 884, 887-88 (N. D. Cal. 2009); United States ex rel. Fry v. Health Alliance of Greater Cincinnati, No. 03-167, 2008 U.S. Dist. LEXIS 102411, at *37 (S.D. Ohio Dec.

18, 2008).

I do not see how Relator reasonably could be required to identify at the pleading stage a specific false claim submitted to the Government by a third party (perhaps doctors or a pharmacy). On the contrary, "requiring production of actual documentation with the complaint [would require] a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." Grubbs, 565 F.3d at 190. Indeed, requiring every relator alleging the indirect submission of fraudulent claims to identify in his complaint a specific false claim would effectively eliminate part of the False Claims Act. See 31 U.S.C. § 3729(a)(1) (any person who "presents, or *causes to be presented*, a false or fraudulent claim for payment . . ., is liable to the United States government for a civil penalty") (emphasis supplied). I am obligated to interpret federal statutes, not read them out of existence. See Singh-Kaur v. Ashcroft, 385 F.3d 293, 305 (3d Cir. 2004) ("An indisputable axiom of statutory construction is that whenever possible each word in a statutory provision is to be given meaning and not to be treated as surplusage.") (internal quotations omitted).

Although Relator was not obligated to identify a particular false claim, he was obligated to "use an alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud," thus placing Genentech "on notice of the precise misconduct with which [it is] charged," and safeguarding "against spurious charges of immoral and fraudulent behaviors." Rolo, 155 F.3d at 658; Seville, 742 F.3d at 791. This Relator has done. As I have discussed, he has set out Genentech's alleged actions from 2000 through "at least December 2002" to bribe doctors and other health care providers to write thousands of Rituxan prescriptions for non-approved uses. He has described the kinds of bribes in some detail. He has alleged that many thousands of prescriptions were written for Medicare/Medicaid patients, resulting in the presentation of many

millions of dollars in false claims to the Government. *(Doc. No. 15 at ¶¶ 23-34.)* There is no mystery or ambiguity to these allegations. Either Genentech lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator's allegations are sufficiently specific both to inform Genentech of the "precise misconduct" charged, and to make it unlikely that Relator has commenced this action in bad faith.

In these circumstances, I conclude that Relator's First Amended Complaint is adequately pled and will deny Genentech's Motion to Dismiss. *(Doc. No. 73.)*

B. Discovery-Based Amendments

Because the First Amended Complaint comports with Rule 9(b), Genentech's objection to Relator's request to amend that Complaint is beside the point. See Saez v. GMC, 305 Fed. Appx. 844, 846 (3d Cir. 2009) (amendments based on evidence learned during discovery are permissible and commonly allowed); see also Werner v. Werner, 267 F.3d 288, 297 (3d Cir. 2001). Even if I were to assume, *arguendo*, that the First Amended Complaint does not comport with Rule 9(b), however, I would grant Relator's request to amend.

Genentech argues that "every circuit court to address the issue agrees that the sufficiency of [a] relator's complaint must rise or fall on the basis of information in the relator's possession *prior* to receiving any discovery." *(Doc. No. 68 at 6.)* By this reasoning, Genentech should object to proposed amendments that are based on *any* of the discovery Relator obtained from the Department of Justice. In fact, Genentech objects only to those amendments it believes are based on those documents the DOJ had earlier obtained from Genentech. The Company does *not* object to amendments it believes Relator based on the documents the DOJ had obtained from other federal agencies. See Doc. No. 68, Ex. B (outlining Genentech documents on which the amendments are

purportedly based). Presumably this is because the authority Genentech offers precludes only amendments to a *qui tam* complaint based on discovery obtained *directly* from the *qui tam* defendant. Genentech offers no authority – and I can find none – barring amendments based on discovery the relator obtained from the Government. Indeed, as I have discussed, courts have suggested just the opposite: that there is no need to relax the Rule 9(b) pleading standard in a *qui tam* case if the relator can incorporate into his complaint allegations based on discovery he has obtained from the Government. See Karvelas, 360 F.3d at 230 ("In many of these cases, the information needed to fill the gaps of an inadequately pleaded complaint will be in the government's hands."); see also Russell, 193 F.3d at 308 (refusing the relator's request to take discovery from the defendant to bolster his complaint "because documents containing the requisite information were possessed by other entities, such as the Healthcare Financing Administration [now the Centers for Medicare and Medicaid Services]").

Genentech thus asks me to disallow *qui tam* amendments purportedly based on documents that Relator obtained from the DOJ because those documents may have been provided to the DOJ by Genentech. Once again, Genentech's request has no legal support. On the contrary, although it did not in its "Statement of Interest" explicitly address this issue, "the United States submits Genentech has misapplied" the law governing the amendment of *qui tam* complaints. *(Doc. No. 75 at 1.)* Moreover, the policy considerations that I have discussed – precluding some discovery-based amendments in *qui tam* actions– also do not support Genentech's request. If a relator expects the DOJ vigorously to investigate his allegations, he will not file a "bare bones" complaint in the hope of later amending it with evidence the DOJ obtained during its investigation. Russell, 193 F.3d at 309. Indeed, the less a relator brings to the DOJ, the less likely the DOJ is to conduct *any*

investigation. Similarly, if the DOJ believes a *qui tam* complaint warrants investigation, allowing the relator to use information the DOJ learns during that investigation is not likely to encourage "parasitic" litigation intended only to extort a settlement from the Defendant. Karvelas, 360 F.3d at 231.

Finally, Genentech has ignored that the DOJ obtained over seven million documents during its investigation – some from other federal agencies; some from Genentech. Although Genentech purports to object only to those amendments based on documents the DOJ obtained from Genentech, the Company would, presumably, also object to amendments based on agency-provided documents if the agency also obtained those documents from Genentech. Drawing the distinction Genentech seeks would thus prove endlessly reductive: Genentech could well object to those amendments that are based on any documents the Company initially provided, even if they passed through more than one federal agency before they were provided to the DOJ and then to Relator. Requiring Relator to establish the "genealogy" of all seven million documents he obtained from the DOJ would likely make it impossible for him to proceed.

In these circumstances, I conclude that requiring courts to bar amendments based on evidence obtained indirectly from the *qui tam* defendant could effectively preclude any discovery-based amendments, thus significantly impugning private enforcement of the False Claims Act. Once again, I am not prepared to write part of the statute out of existence. Accordingly, I will grant the Relator's Motion to Amend. *(Doc. No. 63.)*

V. CONCLUSION

In sum, I conclude that the First Amended Complaint is adequately pled – thus rendering moot Genentech's opposition to Relator's Motion to Amend. *(Doc. No. 73.)* In the alternative, I also

conclude that Relator may amend his First Amended Complaint with documents he obtained from the DOJ. *(Doc. No. 63.)*

I am not insensitive to the concerns expressed by Genentech. Given the imperatives of civil litigation, allowing a False Claims Act suit to go forward will impose significant costs on even the most innocent defendant. The remedies Genentech proposes, however, would require me to re-write the False Claims Act, creating significant and often insuperable obstacles to innumerable *qui tam* actions in the hope of deterring those that should not have been brought in the first place. I do not have either the authority or the inclination to do what Genentech asks.

An appropriate Order follows.

BY THE COURT.

/s/ Paul S. Diamond

Paul S. Diamond, J.